Safe Chain
Solutions 822
Chesapeake Drive
Cambridge, MD
21613

Title:	**Standard Operating Procedures for Vendor and Transaction History Authentication**
Issue Date	**5/2/2015**
Effective Date:	**5/9/2015**
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PURPOSE:

To ensure the correct actions are taken with Transaction Histories of all product shipped to and from Safe Chain Solutions (SCS) and when appropriate, vendor authentication is performed as required by the most stringent law or regulation and in compliance with the Code of Federal Regulations Sections 21CFR§203.3, 21CFR§203.50, 21CFR§203.60.

INSTRUCTIONS:

Transaction History Coordinator will know how to verify, authenticate, create, and properly maintain Transaction Histories.

DEFINITIONS:

1. SCS Office, Cambridge, MD – The space located at 822 Chesapeake Drive, Cambridge, MD 21613 (To be referred to as "Office" hereinafter).
2. Transaction History – *Identifying Statement for Sales by Unauthorized Distributors* that identifies each prior sale, purchase, or trade of a prescription drug, and includes the proprietary and established name of the drug; dosage; container size; number of containers; the drug's lot or control number; the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and the date of each previous transaction. A Transaction History is required before the wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy.
3. Electronic Transaction History System
4. NDC – National Drug Code.
5. Authorized Distributor of record– a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

GUIDELINES:

1. All products received at a SCS distribution center from wholesale distributors shall include a Transaction History.
2. A cause for Authentication shall be conducted if there is any reason to believe that the drugs purchased from another wholesale distributor are counterfeit, suspect of counterfeit, misbranded or adulterated. (See Procedures)
3. A cause for Authentication shall be conducted if there is any reason to believe that the drugs were previously distributed to a pharmacy or via a special pricing contract, in violation of VAWD standards.
4. Notify your manager right away if product cannot be verified.
5. Proper authorities to contact in case of suspected counterfeit product that cannot be verified are Maryland Board of Pharmacy and the Food and Drug Administration within three (3) days.
6. A Transaction History shall be created for all prescription drugs distributed by SCS.

7. Transaction Histories shall be available for inspection and photocopying by authorized Federal, State or local law enforcement agency officials for a period of six (6) years after the date of their creation (the "Retention Period").
8. Transaction History records (both electronic and hard copy versions) will be kept at this office and shall be readily available for authorized inspection during the retention period. Records that are not electronically retrievable at the time of request by an authorized official shall be made available for inspection within two (2) working days of the request.
9. All vendors SCS does business with shall be authenticated by verifying their wholesale distribution license for their state and SCS shall maintain a list of all vendors and their license numbers as well as a hard copy of their license which shall be updated annually.

PROCEDURES:

1. When product is received, verify there is a Transaction History for the product. If no Transaction History is included with the product, contact the vendor. Once you have the Transaction History, verify the product information on the Transaction History matches the actual product received.
2. If there is any reason to believe that the product is counterfeit, suspect of counterfeit, misbranded or adulterated, conduct a For Cause Authentication by verifying the following information for ALL of the owners of the product back to the manufacturer:
   a) The date of purchase
   b) Lot number
   c) Sales invoice number and
   d) Contact information including name, address, telephone number and email address for all wholesalers up to the purchase from the manufacturer.
   e) Notify your manager right away if product cannot be verified.
3. When Transaction History is completed, it will be saved and stored in the purchase order Transaction History file.
4. Once product ships, corresponding Transaction History will be printed and sent to product recipient.
5. If a product is returned from the customer, Transaction History will be corrected to reflect additional locations until disposed of or distributed again. In the case of the product being resold by SCS client, another additional location will be added.
6. Establishing the Legitimacy of Prescription Drugs and/or Devices
   a) It is the policy of SCS to only purchase product directly from manufacturers or a distributor that purchases directly from the manufacturer.
   b) Establishing the Legitimacy of Prescription Drugs and/or Devices purchased directly from a manufacturer source:
      - The T3 must reflect that the product came directly from the manufacturer.
      - SCS will verify that Transaction Information exactly matches those products received.
      - SCS shall make every reasonable effort to verify authenticity of merchandise received and in conjunction, make every reasonable effort to comply with T3 analysis and supplier licensing to verify the authenticity of received merchandise.
      - If unable to authenticate a T3, notification will be made to the Board of Pharmacy and Food and Drug Administration within three business days.
   c) Establishing the Legitimacy of Prescription Drugs and/or Devices purchased directly from a distributor that purchases directly from a manufacturer:

- The T3 must reflect that there are only two entities listed on the T3, the manufacturer and the distributor.
- SCS will verify that Transaction Information exactly matches those products received.
- SCS shall make every reasonable effort to verify authenticity of merchandise received and in conjunction, make every reasonable effort to comply with T3 analysis and supplier licensing to verify the authenticity of received merchandise.
- If unable to authenticate a T3, notification will be made to the Board of Pharmacy and Food and Drug Administration within three business days.

7. FDA Guidelines on Suspect Product
   a) Trading Partners and Product Sourcing
      - Be alert for offers of product for sale at a very low price or one that is "too good to be true."
      - Purchasing from a source new to the trading partner.
      - Receiving an unsolicited sales offer from an unknown source. Trading partners might receive unsolicited offers or advertisements through an email, a fax, a telephone call, or an in-person sales call from a person or entity with whom they do not have an established business relationship.
      - Purchasing on the Internet from an unknown source. Trading partners might be searching for a better price on the Internet or for a product that they cannot obtain from their usual source, and might be tempted to turn to a person or entity with whom they do not have an established business relationship.
      - Purchasing from a source that a trading partner knows or has reason to believe has transacted business involving suspect products, such as:
        - A trading partner that has been involved in business transactions where they sold or delivered suspect or illegitimate product.
        - A trading partner that has a history of problematic or potentially false transaction histories or pedigrees, such as those that contain misspelled words or incomplete information.
        - A trading partner that is reluctant to provide a transaction history or pedigree associated with the product being purchased, or does not do so in a timely manner.
        - Transaction information, a transaction statement, and/or transaction history that appears to be incomplete or suspicious
   b) Supply, Demand, History, and Value of the Product
      - Product that is generally in high demand in the U.S. market.
      - Product that is in higher demand because of its potential or perceived relationship 166 to a public health or other emergency (e.g., antiviral drugs).
      - Product that has a high sales volume or price in the United States.
      - Product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs).
      - Product that has been previously or is currently the subject of a drug shortage
      - Product that has been or is the subject of an illegitimate product notification under the DSCSA or other alert or announcement related to drug quality.
      - Product that has been or is the subject of an FDA counterfeit or cargo theft alert
   c) Appearance of the Product
      - Appearance of a package or a container used for transport (e.g., case or tote) that seems

suspicious (e.g., it has a label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise).

- Package that uses foreign terms, such as a different drug identification number rather than the National Drug Code (NDC).
- Package that is missing information, such as the lot number or other lot identification, or the expiration date.
- Package that is missing anti-counterfeiting technologies normally featured on the FDA-approved product that are easily visible to the eye, such as holograms, color shifting inks, or watermarks.
- Finished dosage form that seems suspicious (e.g., it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints
- Closely examine the package and the transport container (such as the case or tote):
    - To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered).
    - To see if it has changed since it was last received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received).
    - To see if product inserts are missing or do not correspond to the product.
    - For shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source.
- Closely examine the label on the package, or the label on the individual retail unit, if applicable, for:
    - Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug.
    - Any altered product information, such as smudged print or print that is very difficult to read.
    - Misspelled words.
    - Bubbling in the surface of a label.
    - Lack of an Rx symbol.
    - Foreign language with little or no English provided.
    - Foreign language that is used to describe the lot number.
    - A product name that differs from the name of the FDA-approved drug.
    - A product name that is the product name for a foreign version of the drug.
    - A product that is transported in a case or tote, when not expected under the circumstances.
    - Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container.